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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,424	06/28/2002	Muhammed Majeed	108064-00049	2480

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,424	MAJEED ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *148,150,~~151~~,175 and 177-190* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *148,150,~~151~~, 175, 177-190* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 21, 2005 has been entered.

Claim Rejections 35 U.S.C. 112

a. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 148, 177 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recites the particularly percentage of a composition consisting essentially of four boswellic acids. The application as originally filed lack support for such range. See, pages 17-19 herein. It is noted the application discloses range of beta-boswellic acid of 5-95% for a composition comprising two boswellic acids, not four boswellic acids. This is a new matter rejection.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 148 and 177 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The claims are directed to the employment of a composition comprising essentially of 4 compounds with the percentage of 5-95%, 5-95%, 1-95%, and 1-95% respectively. It is not clear that if one compound is 95%, as defined in the claim, how the rest of compounds be within the amount range as defined. The claims are indefinite as to the percentages of each and every compound therein.

Claims Rejections 35 U.S.C. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 148, 150, 151, 175, 177-190 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ammon et al. (EP 0552657, IDS) in view of applicants' admission.

8. Ammon teaches that (as applicants admitted at page 1 of the application) each and every of the β-boswellic acid, its physiological acceptable salts, derivatives, including those herein employed, are known to be useful as anti-inflammatory agent. Ammon further teaches that compositions, including plant preparation) comprising the β-boswellic acid, or its derivatives, are useful for prophylaxis and treatment of inflammation. See the abstract. Applicants further admitted that plant preparation comprising the β-boswellic acids has been used for treating inflammatory disorders. See page 1 in the specification.

9. The cited reference as a whole does not teach expressly the employment of a composition comprising β-boswellic acids in the particular percentages as herein defined.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a composition as herein defined for treating inflammatory disorders.

A person of ordinary skill in the art would have been motivated to make a composition as herein defined for treating inflammatory disorders because each of the active ingredients herein are known anti-inflammatory agent. It is prima facie obvious to combine two or more compounds each of which is taught in the prior art to be useful for same purpose in order to form a composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is directed to the employment of a combination of four known anti-inflammatory agents for anti-inflammatory therapy sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. The particularly percentages herein would have been obvious as it would have been an obvious alternative, absent evidence to the contrary. The percentages are also obvious because such percentages would naturally presented in plant materials, and a plant preparation of β-boswellic acid composition would likely to have such percentages of the β-boswellic acids.

Claims 148, 150, 175 and 177-190 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Koji et al. (JP 0428809, see the English translation).

Koji et al. in JP 0428809 discloses that specific boswellic acids such as β-boswellic acid, acetyl-beta-boswellic acid, 11-keto-p-boswellic acid, and acetyl-l l-keto-β-boswellic acid (see formula I of the structures at page 2 of the English translation) are useful in pharmaceutical

compositions and in the method for treatment of inflammatory disorders such as chronic rheumatoid arthritis and psoriasis (see page 3-4). Moreover, Koji et al. also discloses the methods or processes how obtain and separate each instant boswellic acid from boswellic acids mixture in the plants. Further, the structural formula disclosed in JP 0428809 clearly encompasses all four instant boswellic acids. JP 0428809 discloses the composition comprising p-boswellic acid, acetyl-β-boswellic acid, 11-keto-β-boswellic acid, or acetyl-l l-keto-j-boswellic acid, acetyl-l l-keto-β-boswellic acid in their effective amounts. See Example 1-6, and the testing data of the Examples therein as working examples.

JP 0428809 does not expressly disclose the instant particular percentage or range of each of four boswellic acids employed in pharmaceutical compositions for methods for treatment of particular autoimmune diseases.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine particular percentage or range of each of four boswellic acids employed in pharmaceutical compositions for methods for treatment of particular autoimmune diseases wherein at least 5% w/w of β-boswellic acid, at least 5% w/w of acetyl-β-boswellic acid, at least 15% w/w of 1 l-keto-β-boswellic acid and at least 14% w/w of acetyl-l l-keto-β-boswellic acid or other instant particular amounts of boswellic acids. One having ordinary skill in the art at the time the invention was made would have been motivated to determine particular percentage or range of each of four boswellic acids employed in pharmaceutical compositions for methods for treatment of particular autoimmune diseases wherein at least 5% w/w of β-boswellic acid, at least 5% w/w of acetyl-β-boswellic acid, at least 15% w/w of 11-keto-β-boswellic acid and at least 14% w/w of acetyl-l l-keto-β-boswellic acid or other instant particular

amounts of boswellic acids, since the testing results and working examples of the instant boswellic acids useful for treating particular autoimmune diseases are known according to JP 0428809.

Therefore, the determination and optimization of effective amounts of known active agents to be administered based on the known parameters, testing results and working examples provided by JP 0428809, are considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the ad to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 1980).

Claims 148, 150, 151, 175 and 177-190 are rejected under 35 U.S.C. 1O3(a) as being unpatentable over by Taneja et al. (EP 0755940, of record).

Taneja et al. discloses that boswellic acids herein such as p-boswellic acid, acetyl-β-boswellic acid, 11-keto-β-boswellic acid, and acetyl-l l-keto-β-boswellic acid (Formula I-IV therein at page 3) are useful in pharmaceutical compositions and in the method for treatment of inflammatory diseases including arthritis in humans since these boswellic acids exhibit anti-inflammatory action. See page 2 lines 49-50. Taneja et al. also discloses that the pharmaceutical composition therein comprising these β-boswellic acids in specifically effective amounts, e.g., 35-55% w/w of β-boswellic acid (which reads on at least 5% w/w), 25-45% w/w of acetyl-β-boswellic acid (which reads on at least 5% w/w), 4-14% w/w of 1 l-keto-β-boswellic acid, and 3-13% w/w of acetyl-l l-keto-j-boswellic acid (see page 5 lines 15-26).

Taneja et al. does not expressly disclose the effective amounts of 11-keto-β- boswellic acid and acetyl-1 l-keto-β-boswellic acid employed in pharmaceutical compositions for methods for treatment of autoimmune diseases in which at least 15% w/w of 11-keto-β-boswellic acid and at least 140/c w/w of acetyl-1 l-keto-β-boswellic acid.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine the effective amounts of 1 l-keto-β-boswellic acid and acetyl-1 l-keto-p-boswellic acid employed in pharmaceutical compositions for methods for treatment of autoimmune diseases in which at least 15% w/w of 11-keto-β-boswellic acid and at least 14% w/w of acetyl-1 l-keto-β-boswellic acid.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of 1 l-keto-β-boswellic acid and acetyl-1 l-keto-β-boswellic acid employed in pharmaceutical compositions for methods for treatment of autoimmune diseases in which at least 15% w/w of 1 l-keto-β- boswellic acid and at least 14% w/w of acetyl-1 l-keto-β-boswellic acid, since the determination and optimization of effective amounts of known active agents to be administered based on the known effective amounts according to Taneja et al, are considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 1980). Moreover, one of ordinary skill in the art would recognize that autoimmune diseases broadly encompass inflammatory diseases. Hence, the teachings of Taneja et al. have clearly provided the motivation for the instant invention.

Thus the claimed invention as a whole is seen prima facie obvious over the combined teachings of the prior art.

Response to the Arguments

Applicants' amendments and remarks submitted September 6, 2005 and September 21, 2005 have been fully considered, but are unpersuasive with respect to the rejections under 35 U.S.C. 103.

Applicants contend that the claimed invention would have not been obvious over Koji et al. as Koji et al. explicitly remove two of the four boswellic acids, leave only two boswellic acids. The arguments are not persuasive. Note, question under 35 U.S.C. 103 is not merely what reference expressly teach, but what they would have suggested to one of ordinary skill in the art at the time the invention was made; all disclosures of prior art, including unpreferred embodiments, must considered. In re Lamberti and Konort (CCPA), 192 USPQ 278. It is note that Koji teach all the compounds herein are useful as therapeutical agents for treating chronic rheumatoid arthritis. See, pages 2-3 of the translation.

10. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., without other boswellic acids) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicants contend that Taneja et al. require all of the six boswellic acids while the claimed invention only have four of them. The arguments are not persuasive. First it is noted that the composition employed herein

"consisting essentially" four boswellic acids, which do not excludes other boswellic acids. See, page 17, lines 1-8, wherein the composition defined as comprising other boswellic acids, with each of the other boswellic acids less than 1% of the total composition. Further, the general teaching of Taneja et al. do not require that the other boswellic acids be more that 1%. See, e.g., claims 1 and 2 therein.

11. For the reasons discussed above, all the claims have been properly rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
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